Kansas Drug Utilization Review Newsletter

Health Information Designs, LLC *Spring 2017*

Welcome to the Spring 2017 edition of the "Kansas Drug Utilization Review Newsletter," published by Health Information Designs, LLC (HID). This newsletter is part of a continuing effort to keep the Medicaid provider community informed of important changes in the Kansas Medical Assistance Program (KMAP).

Helpful Web Sites

KMAP Web Site
https://www.kmap-state-ks.us/

KDHE-DHCF Web Site
http://www.kdheks.gov/hcf/

KanCare Web Site
http://www.kancare.ks.gov/

Fee-For-Service (FFS) Helpful Numbers

Provider Customer Service (Provider Use Only)
1-800-933-6593

Beneficiary Customer Service
1-800-766-9012

KMAP PA Help Desk
1-800-285-4978

In This Issue:

Codeine and Tramadol Safety Alert

Opioid use has had a profound impact on the medical industry for several years. Of late, an increased knowledge of the safety profile after short- and long-term usage has helped to close the gap on correct prescribing techniques.

In April 2017, the FDA issued a safety alert "restricting the use of codeine and tramadol in children. Children under 12 years and some adolescents younger than 18 years (especially those with certain genetic factors, obesity, or obstructive sleep apnea and other breathing problems) should not use medicines containing these drugs because of increased medical risks, including slowed or difficult breathing and death. The FDA is also recommending against the use of codeine and tramadol medicines in breastfeeding mothers due to possible harm to their infants, including excess sleepiness, serious breathing problems, or death. The FDA is requiring several labeling changes to all prescription medicines containing these drugs. Healthcare professionals should be aware that tramadol and single-ingredient codeine medicines are FDA approved only for use in adults, and should consider recommending OTC or other FDA-approved prescription medicines for cough and pain management in children younger than 12 years and in adolescents younger than 18 years. The FDA also reminds health care professionals that cough is often secondary to infection and not serious, usually resolving on its own and not requiring treatment."

The FDA also recommends against the use of codeine and tramadol medicines in breastfeeding mothers due to possible harm to their infants, including excess sleepiness, difficulty breastfeeding, or serious breathing problems that could result in death.

Sixty-four worldwide cases of respiratory depression, including 24 deaths, in children were reported between January 1969 and May 2015 with the use of codeine. Codeine is converted to morphine by CYP2D6. Tramadol was identified in nine cases, including three deaths. Both tramadol and its pharmacologic active metabolite (O-desmethyltramadol) have absolute bioavailability of 75%.

Codeine and Tramadol Safety Alert, cont.

Changes to the labels of all prescription medications containing these drugs are now required. The following changes further limit the use beyond the 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids:

- Contraindication alert to the drug labels of codeine and tramadol warning that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- Contraindication alert to the tramadol label warning against its use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids.
- Warning to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- Warning to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants.

Medications Containing Codeine/Dihydrocodeine	Medications Containing Tramadol
• Codeine sulfate • Fioricet/codeine • Fiorinal/codeine #3 • Ascomp-codeine • Soma/codeine • Tylenol with codeine (Tylenol #3, Tylenol #4) • Promethazine VC/codeine • Promethazine/codeine • Triacin-c • Tuxarin ER • Tuzistra-XR • Synalgos-DC • Generic products containing codeine	• Ultram • Ultram ER • Ultracet • ConZip • Synapryn FusePaq • Generic products containing tramadol

*The above products many not be covered for adults with fee-for-service (FFS) coverage

To report a serious problem to MedWatch, either, 1) complete and submit the report online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home, or 2) download the form at https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf or call 1-800-332-1088 to request a reporting form. Complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Opioid Risks

Not only has the FDA issued warnings regarding the use of opioids in children, but has addressed the potential dangers of using opioid-receptor agonists with CNS depressants (e.g., benzodiazepines, alcohol, etc) in adults. The combination may result in profound sedation, respiratory depression, coma, and death. Opioid cough medications should be avoided in patients taking benzodiazepines, other CNS depressants, or alcohol.

Opioid Risks, cont.

Additionally, there have been new boxed warnings approved regarding an array of caution, including abuse, addiction, drug interactions, and risks associated with use.

See below for a summary for these updates.

Demerol (meperidine) Percodan (oxycodone/aspirin)	Boxed Warning regarding addiction, abuse, and misuse; life-threatening respiratory depression; accidental ingestion; neonatal opioid withdrawal syndrome; cytochrome P450 3A4 interaction; risks from concomitant use with benzodiazepines or other CNS depressants; and monoamine oxidase inhibitors interactions. Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.
Librium (chlordiazepoxide)	Boxed Warning regarding risks from concomitant use with opioids. Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death.
Sufenta (sufentanil)	Boxed Warning regarding addiction, abuse, and misuse, which can lead to overdose and death.
Hycofenix (hydrocodone bitartrate/pseudoephedrine hydrochloride/guaifenesin)	Boxed Warning regarding the risks from concomitant use with benzodiazepines or other CNS depressants. Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Opioid cough medications should be avoided in patients taking benzodiazepines, other CNS depressants, or alcohol.
Promethazine hydrochloride/codeine phosphate	Boxed Warning regarding the risks from concomitant use with benzodiazepines or other CNS depressants. Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Opioid cough medications should be avoided in patients taking benzodiazepines, other CNS depressants, or alcohol. The Boxed Warning also warns about the risk of respiratory depression in children, and risk of respiratory depression and death in children related to ultra-rapid metabolism of codeine to morphine.
Tussigon (hydrocodone bitartrate/homatropine methylbromide)	Boxed Warning regarding risks from concomitant use with benzodiazepines or other CNS depressants. Opioid cough medications should be avoided in patients taking benzodiazepines, other CNS depressants, or alcohol.

References:

1) U.S. Food and Drug Administration. "Codeine and tramadol medicines: drug safety communication - restricting use in children, recommending against use in breastfeeding women." April 20, 2017. Available at https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm554029.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.

2) U.S. Food and Drug Administration. FDA drug safety communication: FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women. April 20, 2017. Available at https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm.

3) Facts & Comparisons eAnswers. St. Louis, MO: Wolters Kluwer Health Inc.; 2017. Available at http://online.factsandcomparisons.com. Accessed May 2017.

Generic Medications

Recently Approved Generic Drugs:

February 2017	March 2017	April 2017
Cefixime (Suprax) Logilia ulipristal (Ella) Sodium sulfate, potassium sulfate, magnesium sulfate (Suprep Bowel Prep Kit)	Zileuton ER (Zyflo CR) Melphalan (Alkeran) Silodosin (Rapaflo)	Tazarotene (Tazorac) Dexlansoprazole (Dexilant) Ezetimibe-atorvastatin (Liptruzet) Prednisone DR (Rayos) Ezetimibe-simvastatin (Vytorin) Vigabatrin (Sabril) Azelastine-fluticasone (Dymista)

Upcoming Generic Drugs:

Generic Name	Brand Name	Anticipated Launch
Atomoxetine	Strattera	May 26, 2017

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